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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,108	02/04/2004	Jantzen A. Cole	702.117	4849

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EXAMINER	
WALKER, AMANDA H	

ART UNIT	PAPER NUMBER
3709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,108	COLE ET AL.	
	Examiner	Art Unit	
	Amanda H. Walker	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-30-2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The compressive strength ranges stated fall outside of the prior stated limitations ("exceeding 50" does not fall within the range of "about 45-49 MPa" and "exceeding 106" does not fall within the range of "approximately 88 Mpa").

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (U.S. Patent No. 5,614,206).

Randolph et al. teaches a powder comprising calcium sulfate hemihydrate (3:55-60). The powder is mixable with diluent (3:60-65), and the diluent to powder weight ratio of .22:1 - 1:1. This mixture forms a resorbable (4:45-50) bone graft material (15:5-10).

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (U.S. Patent No. 5,614,206).

Randolph et al. teaches a powder comprising calcium sulfate hemihydrate (3:55-60). The powder is mixable with diluent (3:60-65), and the diluent to powder weight ratio of .22:1 - 1:1. This mixture/paste forms a resorbable (4:45-50) bone graft material (15:5-10). Paste like properties are inherent considering that the mixture can be molded to form a pellet (2:10-25).

Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (U.S. Patent No. 5,614,206).

Randolph et al. teaches a powder comprising calcium sulfate hemihydrate (3:55-60). The powder is mixable with diluent (3:60-65), and the diluent to powder weight ratio of .22:1 - 1:1. Water used in this procedure would inherently be sterile, as are all ingredients included in objects destined for swallowing or implantation. Impurities/ accelarants such as calcium sulfate dihydrate may or may not be present (2:40-45), which encompasses the claimed range. An additive in the range of 0-25% (4:5-15) insinuates that the calcium sulfate hemihydrate is present in a range of 75-100%. This mixture forms a resorbable (4:45-50) bone graft material (15:5-10). Injectability and paste like properties are inherent considering that the mixture can be molded to form a pellet (2:10-25).

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al. (U.S. Patent No. 5,614,206).

Randolph et al. teaches a bone graft material (15:5-10) comprising calcium sulfate hemihydrate (3:55-60), which inherently forms thick, stubby, rod like crystals, as is evidenced by Tiemann et al. (page 1267).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). The diluent to powder weight ratio is .22:1 - 1:1 (3:60-65), which encompasses the claimed range. Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). Randolph et al. and Constantz et al. are combinable because they are from the same field of endeavor, namely, bone implant materials. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) as evidenced by Tiemann et al..

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that

the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10). Calcium sulfate hemihydrate inherently forms thick, stubby, rod like crystals, as is evidenced by Tiemann et al. (page 1267).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). Randolph et al. and Constantz are combinable because they are from the same field of endeavor, namely, bone implant materials. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Constantz (U.S. Patent No. 6,375,935).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). Randolph et al. and Constantz et al. are combinable because they are from the same field of endeavor, namely, bone implant materials. At the time of the invention, it would

have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Randolph et al. does not teach that the material has a compressive strength above *15 MPa within one hour, 45-49 MPa within one hour, or over 50 MPa within one hour* after injection. However, Constantz teaches a similar material which sets in an in vivo fluid environment in 4-10 minutes into a solid having a compressive strength of at least about 40-70 Mpa (Claim 9). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz, and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients.

Randolph et al. does not teach that the material has a compressive strength above 15 MPa within one hour *after injecting*. However, Constantz implicitly teaches this limitation through testing in an in-vivo fluid environment (7:30-47 and Claim 9). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz, and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

Claims 9-11 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Randolph et al. does not teach that the material has a compressive strength above *15 MPa within one hour, 45-49 MPa within one hour, or over 50 MPa within one hour* after injection. However, Constantz et al. implicitly teaches these limitations considering that time to one half of the compressive strength may be fewer than 3 hours, and the optimal compressive strength is greater than 110 MPa (8:40-50). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz et al., and one would have been motivated to do

so in order to provide quicker in vivo setting, which is more convenient for doctors and patients.

Randolph et al. does not teach that the material has a compressive strength above 15 MPa within one hour, 45-49 MPa within one hour, or over 50 MPa within one hour *after injection*. However, Constantz et al. implicitly teaches this limitation through testing in an in-vivo fluid environment (9:15-25). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz et al., and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Constantz (U.S. Patent No. 6,375,935).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of

Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Randolph et al. does not teach that the material has a compressive strength of at least *6 MPa within 20 minutes* after injection. However, Constantz teaches a similar material which sets in an in vivo fluid environment in 4-10 minutes into a solid having a compressive strength of at least about 40-70 Mpa (Claim 9). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz, and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients.

Randolph et al. does not teach that the material has a compressive strength of at least 6 MPa within 20 minutes *after injecting*. However, Constantz implicitly teaches this limitation through testing in an in-vivo fluid environment (7:30-47 and Claim 9). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz, and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

Claim 12 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Randolph et al. does not teach that the material has a compressive strength of at least *6 MPa within 20 minutes* after injection. However, Constantz et al. implicitly teaches this limitation (10:15-25) (see also MPEP 2144.05 and 2131.03). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz et al., and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients.

Randolph et al. does not teach that the material has a compressive strength of at least 6 MPa within 20 minutes *after injecting*. However, Constantz et al. implicitly teaches this limitation through testing in an in-vivo fluid environment (9:15-25). At the time of the invention, it would have been obvious to a person having ordinary skill in the

art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz et al., and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

Claim 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Constantz (U.S. Patent No. 6,375,935).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Randolph et al. does not teach that the material has a compressive strength of at least *35 MPa or about 55 MPa within 24 hours* after injection. However, Constantz teaches a similar material which sets in an in vivo fluid environment having a compressive strength well in excess of 50 MPa at one day after immersion in distilled

water (7:35-47) (see also MPEP 2144.05 and 2131.03). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz, and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients.

Randolph et al. does not teach that the material has a compressive strength of at least 35 MPa or about 55 MPa within 24 hours *after injecting*. However, Constantz implicitly teaches this limitation through testing in an in-vivo fluid environment (7:30-47). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz, and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

Claims 13 and 14 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, Constantz et al. teaches injecting a similar product (7:30-35). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

Randolph et al. does not teach that the material has a compressive strength of at least *35 MPa or about 55 MPa within 24 hours* after injection. However, Constantz et al. teaches a similar material which sets in an in vivo fluid environment having a compressive strength of 110 MPa in less than 8 hours (8:40-50) (see also MPEP 2144.05 and 2131.03). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz et al., and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients.

Randolph et al. does not teach that the material has a compressive strength of at least 35 MPa or about 55 MPa within 24 hours *after injecting*. However, Constantz et al. implicitly teaches this limitation through testing in an in-vivo fluid environment (9:15-25). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz et al., and

one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Murray (U.S. Patent No. 4,778,834).

Randolph et al. teaches mixing a powder comprising calcium sulfate hemihydrate with a diluent (2:10-20). Injectability and paste like properties are implicit considering that the mixture can be molded to form a pellet (2:10-25). Randolph et al. teaches that the resorbable (4:45-50) pellet can be used as a bone implant (15:5-10).

Randolph et al. does not teach that the material has a compressive strength of about *88 MPa or exceeding 106 MPa within 24 hours* after mixing in a dry testing environment. However, Murray teaches a similar product with dry testing values that obviate these ranges (Table 2 and 13:20-25) (see also MPEP 2144.05 and 2131.03). Randolph et al. and Murray are combinable because they are from the same field of endeavor, namely, bone implant materials. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength taught by Murray, and one would have been motivated to do so in order to provide a bone implant which best mimics the true compressive strength of natural bone.

Randolph et al. does not teach that the material has a compressive strength of at about 88 MPa or exceeding 106 MPa within 24 hours after mixing *in a dry testing*

environment. However, Murray teaches a dry testing environment (13:20-25). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in a dry environment taught by Murray, and one would have been motivated to do so in order to obtain data for comparing the product's mechanical qualities to those of potential competitors.

Other prior art considered applicable to the instant claims but not used in these rejections can be found in the enclosed document entitled "Notice of References Cited".

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda H. Walker whose telephone number is (571)270-3296. The examiner can normally be reached on 9-4, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHW

8-23-07

MARK EASHOO, PH.D.
SUPERVISORY PATENT EXAMINER

29 /Aug/07